2016-1067, -1108, -1111

United States Court of Appeals for the Federal Circuit

AKER BIOMARINE AS, ENZYMOTEC LTD., ENZYMOTEC USA, INC.,

Appellants,

v.

NEPTUNE TECHNOLOGIES AND BIORESSOURCES INC.,

Cross-Appellant.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2014-00003 and IPR2014-00556.

NONCONFIDENTIAL BRIEF FOR CROSS-APPELLANT NEPTUNE TECHNOLOGIES AND BIORESSOURCES INC.

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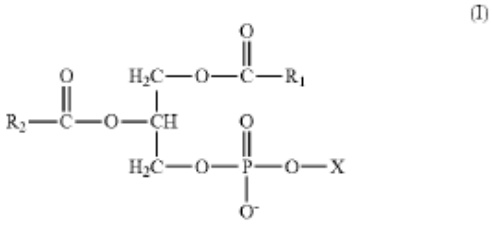
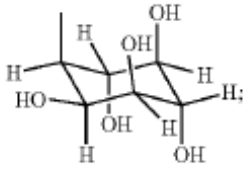
July 1, 2016

U.S. Patent No. 8,278,351, 1-6, 9, 12, 13, 19-29, 32, 35, 36, and 42-46 (Appx0067-70)

1. A krill extract comprising: a phospholipid of the general formula (I),



wherein R1 and R2, each together with the respective carboxyl groups to which each is attached, each independently represents a docosahexaenoic acid (DHA) or an eicosapentanoic acid (EPA) residue, and X is —$CH_2CH_2NH_3$, —$CH_2CH_2N(CH_3)_3$, or



and wherein the extract is suitable for human consumption.

2. The extract according to claim **1**, wherein the extract has a total phospholipid concentration in an amount of about 40% w/w, wherein about represents ±10%.

3. The extract according to claim **1**, wherein the extract has a total phospholipid concentration in an amount of about 45% w/w, wherein about represents ±20%.

4. The extract according to claim **1**, further comprising an additional lipid, wherein the additional lipid is selected from the group consisting of monoglycerides, triglycerides, cholesterols, mixtures thereof, and free fatty acids.

5. The extract according to claim **1**, wherein the extract has a concentration of free fatty acids of about 5% w/w of the lipids in the extract.

6. The extract according to claim **1**, wherein the extract further comprises polyunsaturated fatty acids which comprise at least 15% w/w of the lipids in the extract.

9. The extract according to claims **6**, **7**, or **8**, wherein the polyunsaturated fatty acids are omega-3 fatty acids.

12. The extract according to claim **1**, further comprising a metal.

13. The extract according to claim **12**, wherein the metal is zinc, selenium or a mixture thereof.

19. The extract of claim **1**, wherein one of R1 and R2 is EPA and the other is DHA.

20. The extract of claim **1**, wherein R1 and R2 is EPA.

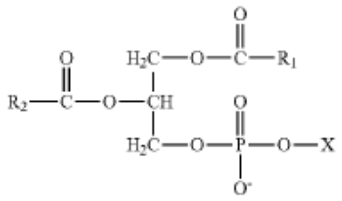
21. The extract of claim **1**, wherein R1 and R2 is DHA.

22. The extract of claim **1**, further comprising an antioxidant.

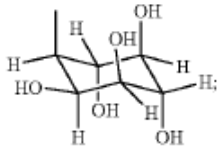
23. The extract of claim **22**, wherein the antioxidant is selected from the group consisting of vitamin A, vitamin E, carotenoid, beta-carotene, astaxanthin, canthaxanthin, flavonoids, and mixtures thereof.

24. A capsule, tablet, solution, syrup, or suspension comprising a krill extract comprising: a phospholipid of the formula (I),

(I)



wherein R1 and R2, each together with the respective carboxyl groups to which each is attached, each independently represents a docosahexaenoic acid (DHA) or an eicosapentaenoic acid (EPA) residue, and X is —$CH_2CH_2NH_3$, —$CH_2CH_2N(CH_3)_3$, or



and wherein the extract is suitable for human consumption.

25. The extract according to claim **24**, wherein the extract has a total phospholipid concentration in an amount of about 40% w/w, wherein about represents ±10%.

26. The extract according to claim **24**, wherein the extract has a total phospholipid concentration in an amount of about 45% w/w, wherein about represents ±20%.

27. The formulation according to claim **24**, further comprising an additional lipid, wherein the additional lipid is selected from the group consisting of monoglycerides, triglycerides, cholesterols, mixtures thereof, and free fatty acids.

28. The formulation according to claim **24**, wherein the extract has a concentration of free fatty acids of about 5% w/w of the lipids in the extract.

29. The formulation according to claim **24**, wherein the extract further comprises polyunsaturated fatty acids which comprise at least 15% w/w of the lipids in the extract.

32. The formulation according to claim **29**, **30**, or **31**, wherein the polyunsaturated fatty acids are omega-3 fatty acids.

35. The formulation according to claim **24**, further comprising a metal.

36. The formulation according to claim **35**, wherein the metal is zinc, selenium or a mixture thereof

42. The formulation of claim **24**, wherein one of R1 and R2 is EPA and the other is DHA.

43. The formulation of claim **24**, wherein R1 and R2 is EPA.

44. The formulation of claim **24**, wherein R1 and R2 is DHA.

45. The formulation of claim **24**, further comprising an antioxidant.

46. The formulation of claim **45**, wherein the antioxidant is selected from the group consisting of vitamin A, vitamin E, carotenoid, beta-carotene, astaxanthin, canthaxanthin, flavonoids, and mixtures thereof.

CERTIFICATE OF INTEREST

Counsel for Cross-Appellant Neptune Technologies and Bioressources Inc. certifies the following:

1. The full name of every party or amicus presented by me is:

Neptune Technologies and Bioressources Inc.

2. The name of the real party in interest represented by me, and not identified in response to Question 3, is:

Neptune Technologies and Bioressources Inc.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or amicus curiae represented by me are listed below.

Neptune Technologies and Bioressources, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Neptune Technologies and Bioressources, Inc. stock.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me at the agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Cooley LLP: Dean Farmer, Jonathan G. Graves, Scott Sukenick, and former Cooley LLP employees Laura J. Cunningham, Stephen L. Altieri and Jing Wang

Date: July 1, 2016

/s/ Jonathan G. Graves
Jonathan G. Graves
Counsel for Cross-Appellant

Table of Contents

Page

Table of Contents
(continued)

Table of Contents
(continued)

CONFIDENTIAL MATERIAL OMITTED

The material omitted from the Statement of Related Cases on pages vii and viii describes litigation between Appellant Aker BioMarine AS and Cross-Appellant Neptune Technologies and Bioressources Inc. The facts and circumstances of this litigation are under seal.

Table of Authorities

Cases **Page(s)**

Table of Authorities
(continued)

Table of Authorities
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Statutes

Other Authorities

Confidential Material Redacted

STATEMENT OF RELATED CASES

[redacted]

In this appeal, Appellants argue, *inter alia*, that the Board should have granted Appellants' rehearing petition seeking consideration after the Board's Final Written Decision of two of the grounds in Appellants' IPR petitions on which the Board did not institute review—anticipation of claims 5 and 28 of Neptune's '351 patent by Maruyama and Fujita. Appellants ask this Court to reverse the Board's denial of rehearing and to remand back to the Board, or alternatively to

grant mandamus relief. [redacted]

Neptune is otherwise not aware of any cases pending in this Court or any other court that will directly affect or be directly affected by this Court's decision in this appeal.

STATEMENT OF JURISDICTION

The Board had jurisdiction over the underlying *inter partes* review proceedings under 35 U.S.C. § 311. The Board issued its final written decision on March 23, 2015, and denied Appellants' petition for rehearing on July 8, 2015. Neptune timely appealed on September 8, 2015. *See* 35 U.S.C. § 142; 37 C.F.R. § 90.3(a)(1), (b)(1). This Court has jurisdiction under 35 U.S.C. §§ 141, 319, and 28 U.S.C. § 1295(a)(4)(A).

PRELIMINARY STATEMENT

In their Preliminary Statement, Appellants argue that Neptune's '351 patent "plainly never should have issued", attacking it as directed to "naturally-occurring molecules in krill" and invalid in view of "overwhelming prior art." Appellants' Br., 1-2. Appellants had a full opportunity to litigate these invalidity challenges, and many other defenses, in an investigation by the U.S. International Trade Commission. On the eve of trial, however, both Appellants opted to become licensees under Neptune's patents, with each agreeing to make a non-refundable lump sum payment for their alleged past infringement. The settlement agreements also allowed Appellants to pursue an IPR proceeding only as to 28 agreed-upon claims of the '351 patent, with the outcome determining Appellants' future royalty obligations. This appeal arises from the Board's Final Written Decision in that IPR.

Despite conducting extensive discovery and prior art searching during the ITC investigation, Appellants were unable to present to the Board even one prior art reference that allegedly expressly anticipates any of the claims at issue. Instead, Appellants relied heavily on a theory of inherent anticipation by one reference (Beaudoin I) supported by a series of flawed "recreation" experiments that produced highly variant results. In asserting obviousness, Appellants relied on a 5-way combination of disparate references containing inconsistent teachings.

The Board upheld two of the challenged claims—5 and 28—while concluding that Appellants had met their burden of proving either inherent anticipation and/or obviousness of the other 26 claims. The Board's anticipation findings based on Beaudoin I resulted from its erroneous determination that the claims cover krill extracts that are unsafe for ingestion by humans, misreading of the process disclosed in Beaudoin I, and willingness to ignore aspects of Appellants' "recreations" that refute inherency. The same claim construction error also infected the Board's obviousness rulings. In addition, the Board's conclusory determination that one of skill would have been motivated to combine the 5 references is not based on substantial evidence, and in fact is contrary to express teaching away evidence in the art relied upon by Appellants.

Appellants' attacks on the Board's rulings on claims 5 and 28 are without merit. The Board's construction of 2.5% to 7.5% for "about 5%" is the broadest reasonable interpretation in light of the specification. Appellants' construction of 0% to 55% makes no sense, and is directly contrary to Appellants' constructions in the ITC case of "about . . . plus or minus percent" terms in other claims. Employing the proper construction, the Board correctly determined that Appellants failed to prove that claims 5 and 28 are obvious.

This Court lacks jurisdiction to consider Appellants' appeal of the Board's denial of their request on rehearing that the Board find claims 5 and 28 anticipated

based on two grounds that were ***not instituted***. And even if the Board's decision were reviewable, it cannot be disturbed, because the Board did not act arbitrarily and capriciously.

The Board's decision upholding claims 5 and 28 should be affirmed, and its findings of anticipation and/or obviousness as to the other 26 claims should be reversed.

STATEMENT OF THE ISSUES

1. Did the Board err in construing "suitable for human consumption" as covering krill extracts that are unsafe for humans to ingest, and in construing "capsule, tablet, solution, syrup, or suspension" as not being limited to preparations of the claimed krill extracts for oral administration?

2. Did the Board err in finding that Beaudoin I inherently anticipates claims 1 and 24 and dependent claims 4, 6, 9, 12, 13, 19-23, 27, 29, 32, 35, 36, and 42-46 based on its incorrect claim constructions, misreading of the heating step taught by Beaudoin I, and failure to properly consider evidence from Appellants' Beaudoin I "recreations" that refutes inherency?

3. Did the Board err in finding claims 1 and 24 and dependent claims 4, 6, 9, 12, 13, 19-23, 27, 29, 32, 35, 36, and 42-46 obvious in view of Appellants' 5-way combination of disparate prior art references based on the Board's erroneous

claim constructions, failure to properly consider evidence of express teaching away, and misapplication of the law?

4. Was the Board's finding that dependent claims 5 and 28 were not obvious supported by substantial evidence?

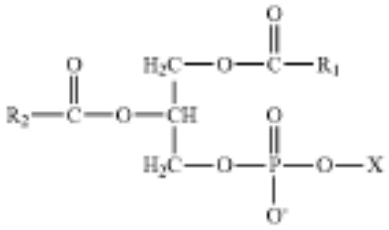
5. Does this Court have jurisdiction to review the Board's denial of Appellants' petition for rehearing seeking findings of anticipation of claims 5 and 28 based on two grounds on which the Board denied institution?

6. If this Court does have such jurisdiction, was the Board's decision arbitrary and capricious, or is mandamus warranted?

STATEMENT OF THE CASE

A. Neptune's '351 Patent and Technology Overview

The '351 Patent, "Natural Marine Source Phospholipids Comprising Polyunsaturated Fatty Acids and Their Applications," has 5 independent and 89 dependent claims (independent claims 1 and 24 and 26 dependent claims are at issue in this appeal). The patent describes and claims a krill extract that is suitable for human consumption and comprises a phospholipid of the formula (I):



wherein R1 and R2 (also called "sn-1" and "sn-2") each independently represent a docosahexaenoic acid (DHA) or an eicosapentanoic acid (EPA) residue. These claimed species of phospholipid with EPA and/or DHA concurrently attached at the sn-1 and sn-2 positions are referred to herein as the "claimed phospholipid."

Krill is a crustacean similar to shrimp that contains a high content of phospholipids, including those that bear the omega-3 fatty acids EPA and/or DHA, which provide a variety of human health benefits. Appx7733-7735, ¶¶8-11. Both before and after the priority date of the '351 Patent, well into the 2000s, krill was considered too difficult for profitable harvesting given its delicate structure and rapid decay rate. Appx7733, ¶9; Appx6751-6752, 218:8-219:3. The industry focused instead on extracting omega-3 fatty acids from fish to produce fish oil.

Breaking away from this industry focus, Dr. Fotini Sampalis, the inventor of the '351 Patent, recognized that krill uniquely contains EPA and DHA esterified to phospholipids. This is distinct from fish oil and most other sources of omega-3s, which contain DHA and EPA (1) bound to triglycerides, and/or (2) as free fatty acids, which are not bound on larger bio-molecules. As a medical doctor, Dr. Sampalis understood that krill phospholipids deliver EPA and DHA to the human body more efficiently than triglycerides or free fatty acids. Appx7733-7735, ¶¶8-13. In fact, Aker (which entered the krill oil market over five years after Neptune developed and pioneered it) markets its product based on the superior benefits of

phospholipid-bound EPA and DHA, which became known largely due to Dr. Sampalis' inventive efforts. *See* Appx7026.

To produce an oil rich in intact phospholipids bearing EPA and/or DHA, Dr. Sampalis diverged from prior art methods by avoiding application of high heat to extracted oil still in its crude form. Extracted krill oil that is unrefined will typically contain high concentrations of water and volatile matter. Appx7735, ¶13. Applying high heat to crude krill oil may cause degradation of the phospholipids and/or fatty acids through processes such as hydrolysis and oxidation. *Id*.

Hydrolysis refers to the degradation of phospholipids by breaking, for example, the ester bonds attaching fatty acid chains to the glycerol backbone of the phospholipid molecule, and thus releasing free fatty acids. Appx7736-7739, ¶¶14-18. Hydrolysis is driven by several factors, including temperature and water and free fatty acid content. *Id*. As water content, heat, or free fatty acid content increases, hydrolysis will also increase. *Id*.

Applying high heat to a krill lipid extract in the presence of oxygen may also cause oxidation of the fatty acids. Appx7739-7740, ¶19. Long chain polyunsaturated fatty acids like EPA and DHA are very sensitive to heat in the presence of oxygen, and heat can cause them to degrade into a variety of oxidation by-products, including shorter chain, and less unsaturated, fatty acids. *Id*.

B. Prior Litigation between the Parties

After Neptune's efforts to negotiate license agreements with Aker and Enzymotec failed, Neptune filed separate patent infringement actions against Aker and Enzymotec in the U.S. District Court for the District of Delaware and a complaint at the ITC (the "ITC Action"). *Notice of Receipt of Complaint*, 78 Fed. Reg. 7811 (Feb. 4, 2013). On October 1, 2013, while the Delaware cases and ITC Action were still pending, Aker filed a petition for *inter partes* review of the '351 patent (IPR2014-0003). Less than two months later, on the eve of trial in the ITC Action, Neptune and Aker entered into a settlement and license agreement. Appx0229-230. Pursuant to the settlement, Aker made a lump sum payment to Neptune for alleged past infringement. *See* https://globenewswire.com/news-release/2013/12/17/597427/10061692/en/Neptune-and-Aker-BioMarine-Reach-Patent-Infringement-Settlement-and-License-Agreement.html (last visited July 1, 2016). The parties agreed to allow IPR2014-0003 to proceed, limited to 28 identified claims (the "Agreed Claims"), and conditioned the existence of future royalty payments on the outcome. *Id*.

On April 4, 2014, more than one year after Neptune filed suit, Enzymotec filed an IPR petition as to the '351 patent (IPR2014-0056). Appx7913-7954. Enzymotec also filed a motion for joinder with the Aker IPR. Appx7955-7963. Later that month, Neptune and Enzymotec entered into a settlement and license

agreement that resolved the ITC Action and related Delaware cases. Like Aker, Enzymotec took a license to Neptune's patent, including the '351 patent, and made a lump sum payment to Neptune for alleged past infringement. *See* http://files.shareholder.com/downloads/AMDA-262U40/2340818670x0x748038/ED2D9EB9-C86E-4F6D-B2C7-0347DEE4808A/ENZY_News_2014_4_28_General_Releases.pdf (last visited July 1, 2016); Appx7978. Neptune consented to Enzymotec's joinder motion, provided that the scope of Enzymotec's IPR would be limited to the same grounds of unpatentability as instituted by the Board in IPR2014-0003. Appx7977.

C. IPR Proceedings

On March 24, 2014, the Board issued its institution decision in IPR2014-0003. The Board instituted on all Agreed Claims and on two grounds: (1) claims 1, 3-6, 9, 12-13, 19-24, 26-29, 32, 35-36, and 42-46 under 35 U.S.C. § 102 as allegedly anticipated by Beaudoin I; and (2) claims 1-6, 9, 12, 13, 19-29, 32, 35, 36, and 42-46 under 35 U.S.C. § 103 as allegedly obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin. Appx0237-266. The Board determined that Aker's other eight grounds of unpatentability were redundant of the grounds on which the Board instituted. Regarding Aker's asserted grounds of anticipation of claims 2 and 25, the Board stated, "we are not persuaded that there is a reasonable likelihood that Aker would prevail at trial with

respect to claims 2 and 25 of the '351 patent, based on anticipation by any one of Beaudoin I, Beaudoin II, Maruyama, Fujita, or Fricke." Appx0252.

Aker requested rehearing only on the Board's decision not to institute a review of claims 2 and 25 as anticipated by Beaudoin I. Appx0283-298. The Board denied Aker's rehearing petition and added that: "[u]pon reconsideration of our Decision regarding these claims [claims 3 and 26], we conclude that Aker has not established a reasonable likelihood that it would prevail on the ground that Beaudoin I anticipates challenged claims 3 and 26 . . . [and] . . . [t]hus, we modify our previous Decision to deny Aker's grounds that Beaudoin I, Beaudoin II, Maruyama, Fujita, or Fricke anticipates claims 3 and 26." Appx0329-330. Accordingly, in IPR2014-0003 the Board refused to institute review of claims 2, 3, 25, and 26 based on anticipation.

Enzymotec filed its IPR petition eleven days after the Board's institution decision in IPR2014-0003. Neptune opposed institution and joinder of Enzymotec in IPR2014-0003 only with respect to anticipation of claims 2, 3, 25, and 26 on the grounds that such institution and/or joinder (1) would be facially inconsistent with the Board's refusal to institute on anticipation of those claims in IPR2014-0003; (2) would effectively allow Enzymotec to broaden the scope of IPR2014-0003, notwithstanding its attempt to join that matter after the statutory one year period; and (3) would allow Enzymotec to evade its contractual obligation to not argue

grounds of alleged unpatentability concerning anticipation of claims 2, 3, 25, and 26. The Board nevertheless granted Enzymotec's joinder motion and instituted in IPR2014-0056 on anticipation of claims 2, 3, 25, and 26. Appx7988-8010.

In its Final Written Decision, the Board:

1. Construed "suitability for human consumption", which appears in independent claims 1 and 24, as encompassing krill extracts that are unsafe for humans to ingest (Appx0008-9);
2. Construed "capsule, tablet, solution, syrup, or suspension", recited in in claim 24, as not being limited to preparations for oral administration (Appx0009-10);
3. Concluded that Beaudoin I:
    - inherently anticipates claims 1 and 24, and 19 dependent claims (4, 6, 9, 12, 13, 19-23, 27, 29, 32, 35, 36, and 42-46) (Appx0021-27);
    - does not anticipate the phospholipid concentration claims (2, 3, 25 and 26) due to variations in Appellants' "recreation" extracts (Appx0023);
    - does not anticipate the free fatty acid concentration claims (5 and 28) due to "about 5%" meaning 2.5% to 7.5%, and Beaudoin's express disclosure of free fatty acid concentrations of greater than 20% (Appx0024);

4. Found that Appellants proved obviousness of all claims except claims 5 and 28 (and 9 and 32, which were not addressed in Appellants' brief) based on the five-way combination argued by Appellants. Appx0027-36.

Appellants then sought rehearing, arguing that the Board should consider, based on its construction of "about 5%," whether Maruyama and Fujita anticipated claims 5 and 28—grounds on which the Board did not institute. Appx0699-716. The Board denied rehearing. Appx0039-44.

SUMMARY OF THE ARGUMENT

I. The Board erred in construing "suitable for human consumption" as encompassing krill extracts that are unsafe for humans to ingest. All independent claims of the '351 patent end with the phrase: "and wherein the extract is suitable for human consumption." This is so regardless of whether the extract is claimed on its own (claims 1 and 94), or whether it is present in a "cosmetic preparation" (claim 70), in a "food, beverage, energy bar, or nutritional supplement" (claim 47), or in a "capsule, tablet, solution, syrup, or suspension" (claim 24). The plain meaning of "suitable for human consumption" refers to a krill extract that is safe and appropriate for humans to ingest. This is also the only reasonable construction based on the specification, which teaches that the claimed krill extracts are

preferably ingested repeatedly in the form of capsules, tables, foods, beverages, and other supplements.

Relying solely on the patent's disclosure of use of the claimed extract in cosmetic preparations, the Board construed all of the claims at issue as encompassing krill extracts that are ***not safe and appropriate for humans to ingest***, such as extracts containing toxic solvents, as long as they can be "consumed" in some other way, such as by "topical administration." The Board's reasoning is fallacious, as the claims to cosmetic preparations do not require that ***the cosmetic preparations*** be ingestible. Rather, those claims—like the claims directed to items clearly intended to be ingested orally and repeatedly—have the same "suitable for human consumption" limitation ***for the krill extract itself***. The only kind of extract that is suitable for every claimed use in the patent is one that is safe to ingest on a regular basis.

The Board similarly erred in failing to limit the construction of "[a] capsule, tablet, solution, syrup, or suspension comprising a krill extract" to preparations for oral administration. By their plain meaning (which is confirmed by the specification), capsules, tablets, solutions, syrups and suspensions are to be consumed orally. Furthermore, all parties' experts agreed that "solution, syrup, or suspension" as recited in claim 24 refers to a liquid preparation for oral administration.

II. The Board committed numerous reversible errors in finding that 22 claims are inherently anticipated. Such a conclusion requires proof that the missing descriptive material is "necessarily present, not merely probably or possibly present, in the prior art"—proof that is lacking in this case.

A) The Board erroneously ignored aspects of Appellants' three purported "recreations" that refuted inherency. All of these recreations were performed differently and yielded different results, and all deviated from Beaudoin I in ways that rendered the extracted oil less susceptible to hydrolysis. Despite that, Appellants were unable to detect the claimed phospholipid in 25% of one set of recreations and discarded a full one-third of another set before testing for the claimed phospholipid.

B) The Board misread the process disclosed in Beaudoin I, eliminating an "important" heating step and fundamentally misunderstanding that a "filtration" step (for separating out solid particles) is not a process that would remove toxic solvents.

C) The Board allowed its flawed construction of "suitable for human consumption" to lead it to an unsupportable conclusion. Beaudoin I discloses krill extracts that contain unacceptably high levels of residual moisture and solvent—orders of magnitude higher than the krill extract disclosed in the '351 patent—and does not indicate the concentration of solvent that remains.

Nonetheless, the Board concluded that Beaudoin I's extract was suitable for human consumption, based on the Board's erroneous construction of the phrase and a statement in Beaudoin I that Dr. Beaudoin "has ingested the different lipid factions of krill. No side effect profile was observed." A person of ordinary skill would not view such an anecdotal report of an ingestion of an undisclosed amount of oil as proof of suitability for human consumption; as Appellants' own expert admitted, "I don't think it's safe [to consume a krill oil] containing an unknown amount of residual solvent."

III. The Board erred in finding obviousness of 24 claims under a strained five-way combination of references directed to very different subjects and applications. Appellants' two primary references (Fricke and Bergerlson) concern academic exercises involving toxic solvents, and the Board erred in divining a motivation to combine these references with other references focused on ingestible products.

The Board also erred in concluding that it would have been obvious to convert toxic extractions made for analytical purposes into extracts suitable for human consumption. Beyond the problem of ***why*** one would be motivated to do so, the Board also failed to identify any teaching of ***how*** to accomplish sufficient removal of toxic solvents. This error is especially glaring considering that prior art

cited by Appellants clearly teaches away from ever using the toxic solvents described in Fricke and Bergelson.

IV. The Board correctly determined that Appellants failed to prove obviousness of Claims 5 and 28. The Board's construction of the term "about 5%" to mean "2.5–7.5%" is the broadest reasonable construction, and is consistent with the specification and Appellants' own prior constructions of terms involving a range of values. Appellants' proposed construction that "about 5%" of free fatty acids means "0-55%" is plainly unreasonable.

Appellants failed to even make a true obviousness argument, relying instead on the concentrations of free fatty acids purportedly disclosed in Fricke. Appellants did not even attempt to show how or why it would have been obvious for one to go from the toxic preparations disclosed in Fricke to an extract suitable for human consumption, let alone one that would possess a concentration of free fatty acids within the claimed range. Furthermore, the Fricke reference itself disclaims the reported concentrations of free fatty acids, referring to them as "probably mostly artifacts."

V. As a matter of law, the denial of Appellants' request for rehearing following the final written decision is not reviewable. As with any decision going to the institution of grounds in an IPR, the Board's refusal to later reconsider grounds that were initially rejected was within its discretion and is not subject to

appellate review. Furthermore, the Board's reasoning was sound, and its decision far from arbitrary and capricious.

ARGUMENT

I. THE BOARD ERRED IN CONSTRUING "SUITABLE FOR HUMAN CONSUMPTION" AND "CAPSULE, TABLET, SOLUTION, SYRUP, OR SUSPENSION"

The Board committed legal error in construing "suitable for human consumption" and "capsule, tablet, solution, syrup, or suspension". Specifically, the Board erred by concluding that the krill extracts of all of the claims can be unsafe for oral ingestion, and that the extracts of claim 24 and its dependents are not limited to formulations for oral administration. The Board's flawed constructions, which are directly contrary to the intrinsic evidence, infected the rest of its analysis.

Claim construction is a legal issue reviewed *de novo*. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). Because the Board relied solely on intrinsic evidence in reaching its constructions of these terms (Appx0008-10), review of any factual findings underlying the Board's constructions is also *de novo*. *Teva*, 135 S. Ct. at 841.

A. "Suitable for Human Consumption"

The Board improperly construed "suitable for human consumption" as covering krill extracts that are unsafe for humans to ingest. The Board's

construction is unreasonable in view of the claim language and the specification. This Court should adopt Neptune's construction—"safe and appropriate for humans to consume, including by oral ingestion."

The claim language itself is the starting point for the claim construction analysis. *Philips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). All independent claims of the '351 patent end with the phrase, "and wherein the extract is suitable for human consumption":

- Claim 1: "A krill extract comprising . . . and wherein the extract is suitable for human consumption."
- Claim 24: "A capsule, tablet, solution, syrup, or suspension comprising a krill extract comprising . . . and wherein the extract is suitable for human consumption."
- Claim 47: "A food, beverage, energy bar, or nutritional supplement comprising a krill extract comprising . . . and wherein the extract is suitable for human consumption."
- Claim 70: "A cosmetic preparation comprising a krill extract comprising . . . and wherein the extract is suitable for human consumption."
- Claim 94: "An Antarctic krill oil extract comprising . . . and [wherein] the extract is suitable for human consumption."

Appx0067-73. Thus, the patentee chose the same term for the krill extract itself—"suitable for human consumption"—regardless of whether the extract is claimed on its own (claims 1 and 94), or whether it is present in a "cosmetic preparation" (claim 70), in a "food, beverage, energy bar, or nutritional supplement" (claim 47), or in a "capsule, tablet, solution, syrup, or suspension" (claim 24).

As evidenced by the claim language, the plain meaning of "suitable for human consumption" refers to a krill extract that is safe and appropriate for humans to ingest. Moreover, this is the only reasonable construction based on the specification, which "is the single best guide to the meaning of a disputed term." *Philips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Indeed, in an IPR the claims should be given their broadest reasonable interpretation ***in light of the specification***. 37 C.F.R. § 42.100(b); *see also In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (under the broadest reasonable construction standard, claims terms are given their ordinary and customary meaning as would be understood by one of ordinary skill at the time of the invention); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. __, 2016 WL 3369425, at *2 (June 20, 2016). The specification teaches that the claimed extracts, which possess "therapeutic properties" (Appx0046, Abstract), are preferably ingested repeatedly and even regularly over an extended period of time. For example, consistent with claim 47, the specification discloses use of the

claimed extracts in "foods, beverages, energy bars, sports drinks, supplements." Appx0063, col. 20:34-36. The specification further discloses use of the extracts "in the treatment or prevention of a variety of disease states," and describes an exemplary beneficial use of the extracts when ingested daily by a 7 year-old girl over a 1.5 month period. *Id.*, col. 20:42-57; Appx0066, col. 26 (Example 3).

The Board nevertheless accepted Appellants' argument that "suitable for human consumption" "broadly covers 'any form of consumption by a human (e.g., oral or topical administration).'" Appx0008-9. In other words, the Board construed all of the claims at issue as encompassing krill extracts that are ***not safe and appropriate for humans to ingest***, such as extracts containing toxic solvents, as long as they can be "consumed" in some other way, such as by "topical administration." In reaching this construction, the Board relied solely on the fact that the specification discloses that "'the phospholipid extract of the invention is also useful in cosmetic preparations, e.g., moisturizing creams, sun-block products and other topical cosmetic products as known in the art'", (Appx0009), and stated that "Patent Owner's analysis does not address the disclosure of 'topical cosmetic products' in the '351 patent." *Id.*

The Board's construction was wrong, as was its statement that Neptune did not address the disclosure of topical cosmetic products. Neptune's Patent Owner Response to Aker's IPR petition stated:

> Patent Owner disagrees that mere suitability for topical application, as opposed to suitability for oral ingestion, is sufficient. While the specification discloses preparations of the extracts for external use, the "suitability for human consumption" requirement applies equally to ***all*** claimed preparations of the extract, including in food, oral, and cosmetic preparations.[1] Thus, any interpretation of "suitable for human consumption" must cover extracts intended for oral ingestion. Patentee could have chosen to claim more broadly an extract suitable for human "application" or "use," but elected to claim and describe an extract suitable for human consumption including, if not primarily, by oral ingestion.

Appx0377 (emphasis in original). *See also* Appx0645-659 (counsel for Neptune reiterating that in all claims, including those directed to cosmetic preparations, the krill extract itself must be suitable for ingestion.)

The Board overlooked Neptune's arguments and myopically focused on its view that makeup is generally not ingestible to conclude that "suitable for human consumption" must be broadly construed to encompass any krill extract that can simply be applied topically, even if it is too toxic to be safely ingested by humans. The Board's reasoning is fallacious. The fact that foods, beverages, and tablets containing a krill extract are meant to be ingested does not mean that a cosmetic preparation containing the same extract must be ingestible. The Board missed the critical point that Claim 70 and its dependents do not require that ***the claimed cosmetic preparations*** be ingestible. Rather, those claims—like the claims directed to food, beverages, nutritional supplements, liquid preparations, and other

[1] Citing to claims 24, 47, and 70 of the '351 patent.

items that are clearly intended to be ingested orally and repeatedly—have the same "suitable for human consumption" limitation ***for the krill extract itself***. The only kind of extract that is suitable for every claimed use in the patent is one that is safe to ingest on a regular basis. The Board's construction allowing for krill extracts that are not safe for oral ingestion is unreasonably broad in view of the claim language and the specification. *See In re LF Centennial Ltd.*, Case No. 2015-1931, 2016 WL 3545686, at 3-4 (Fed. Cir. June 29, 2016) (reversing anticipation and obviousness findings by Board due to unreasonably broad construction that was contrary to the claim language and specification).

B. "Capsule, Tablet, Solution, Syrup or Suspension"

The Board similarly erred in construing "[a] capsule, tablet, solution, syrup, or suspension comprising a krill extract" (claim 24 and its dependents). The specification tracks these claim terms verbatim and makes abundantly clear that they refer to preparations of the claimed krill extracts for oral administration: "Thus, the extract may be formulated for oral administration. For oral administration, the pharmaceutical or nutraceutical compositions may take the form of, for example, tablets or capsules….Liquid preparations for oral administration may take the form of, for example, solutions, syrups or suspensions…."). Appx0063, col. 20:10-24.

The Board concluded:

> Although we agree that that [sic] recitation of "solution, syrup, or suspension" encompasses liquid preparations for oral administration, we decline to interpret the phrase to be limited to liquid preparations for oral administration. Claim 24 recites, for example, solutions comprising a krill extract that are suitable for human consumption. The claim is absent any language that limits "consumption" to oral consumption and we must take care to not import limitations from the specification into the claim.

Appx0010 (citation omitted). The Board's bald conclusion is illogical. By their plain meaning, capsules, tablets, solutions, syrups and suspensions are to be consumed orally. The portions of the specification quoted above unequivocally confirm this plain meaning. And all parties' experts agreed that "solution, syrup, or suspension" as recited in claim 24 refers to a liquid preparation for oral administration. Appx7748-7749, ¶40; Appx6437-6438, 245:20-246:2). The Board's construction is unreasonably broad. This Court should hold that "capsule, tablet, solution, syrup or suspension" refers to oral preparations of the claimed krill extract.

II. THE BOARD COMMITTED NUMEROUS REVERSIBLE ERRORS IN FINDING INHERENT ANTICIPATION OF 22 CLAIMS BY BEAUDOIN I

The Board concluded that Beaudoin I—which is discussed in the specification of the '351 patent and was considered extensively by the examiner during prosecution—inherently anticipates claims 1 and 24, as well as dependent claims 4, 6, 9, 12, 13, 19-23, 27, 29, 32, 35, 36, and 42-46. The Board's

anticipation findings flowed from a cascade of errors, including: (i) the Board's misreading of the heating step taught in Beaudoin I, (ii) its cherry-picking from Appellants' purported Beaudoin I recreation data in contravention of the law on inherent anticipation, and (iii) its improper constructions of "suitable for human consumption" and "capsule, tablet, syrup, suspension, or solution".

Beaudoin I is focused on the extraction of omega-3 fatty acids, in any form, from a wide variety and marine and aquatic sources. Appx0718-21. It does not disclose any benefits from krill oil over more widely utilized resources such as fish, nor does it teach any benefits from omega-3 fatty acids in phospholipid form. *Id.* Moreover, it is undisputed that Beaudoin I does not expressly disclose the claimed phospholipid of the '351 patent. Appellants therefore relied on a theory of inherent anticipation, arguing that Beaudoin I discloses lipid extracts from krill that necessarily contain the phospholipids recited in claims 1 and 24 and that are suitable for human consumption. To support their inherency argument, Appellants submitted various expert declarations and data regarding testing of *E. superba* and *E. pacifica* krill extracts made by their experts allegedly according to the disclosure of Beaudoin I.

The Board found that "[t]he preponderance of evidence on the record suggests that the *E. pacifica* krill extracts disclosed in Beaudoin I necessarily contained the claimed phospholipids." Appx0020 (citing Appx1388-1414, 1421-

1452, ¶¶73-85, 93-98). The Board also concluded that because the reference notes that one of the inventors "ingested" the lipid fractions and "[n]o side effect profile was observed", (Appx0731), Beaudoin I discloses krill extracts "suitable for human consumption" within the meaning of claims 1 and 24. Appx0018, 20-21. Each of several errors committed by the Board warrants reversal.

A. Inherent Anticipation Requires Proof that the Missing Descriptive Material is Necessarily Present in the Prior Art

Anticipation requires that "each and every limitation is found either expressly or inherently in a single prior art reference." *ArcelorMittal France v. AK Steel Corp*., 700 F.3d 1314, 1322 (Fed. Cir. 2012) (internal quotation omitted). To anticipate, a reference must also expressly or inherently disclose the way in which the claimed elements are combined. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010). Anticipation by inherent rather than express disclosure requires proof that the missing descriptive material is "necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (internal quotations omitted). The mere fact that a certain thing ***may*** result from a given set of circumstances is not sufficient to prove inherent anticipation. *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011). In addition, one cannot use the benefit of hindsight to establish the inherency of a claimed limitation. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348-49 (Fed. Cir. 2004).

B. The Board Incorrectly Determined that Beaudoin I Does Not Require a Heating Step

Appellants argued below that Beaudoin I inherently anticipates all of the claims at issue in the IPR because "[t]he processes are virtually identical, as would be the resulting extracts." Appx0109; Appx7943. Neptune argued, *inter alia*, that the Beaudoin I process includes a required step of heating the extracted, crude krill lipids to 125°C for 15 minutes, which is antithetical to the '351 patent's teachings directed to obtaining an extract containing the claimed phospholipid. Appx0383-391.[2] In a brief paragraph, the Board rejected Neptune's argument and concluded that Beaudoin I's heating step is solely for preparation of the extracts for compositional analysis. Appx0019. That conclusion is not based on substantial evidence; on the contrary, it is directly at odds with the disclosure of Beaudoin I and the testimony of both sides' experts.

Beaudoin I emphasizes that the heating step is "important" and required to remove solvent:

[2] Neptune also pointed out dramatic differences between the krill extracts disclosed in the '351 patent and those described in Beaudoin I. For example, Beaudoin I Table 14 discloses krill extracts containing 54.1% and 8.5% "phospholipids or other polar material," while the '351 patent claims krill extracts containing "about 40%" or "about 45%" phospholipids. In its order denying Appellants' rehearing petition, the Board cited these different phospholipid concentrations as indicating that the processes of Beaudoin I and the '351 patent are not, in fact, "virtually indistinguishable." Appx0327-329. In addition, Beaudoin I Table 14 shows free fatty acids of 20.3-23.7%, whereas the '351 patent claims a krill extract with "about 5%" free fatty acids. Appx6714, 181:3-12; Appx7761-7762, ¶63.

> Table 13 shows also that fraction I is comprised of 10.0% of volatile matter and humidity after evaporation of the solvent. For the same test, the fraction II gives a value of 6.8%. **To get rid of traces of solvents**, it is **important** to briefly heat (to about 125°C, for about 15 min) the oil under nitrogen.

Appx0729 (emphasis added); *see also* Appx0726 ("To get rid of traces of organic solvents, lipid fractions I and II are warmed to about 125°C for about 15 minutes under inert atmosphere"). Beaudoin I does not describe this heating step as "optional" or "preferable" as he does with many other steps. Appx0729; *see also* Appx0328-329 (Board noting "preferable" and "optional" aspects of Beaudoin I's process, and concluding that the Beaudoin I and '351 processes "are not, in fact, 'virtually indistinguishable'").

In nevertheless concluding that Beaudoin I's process does not include a heating step, the Board relied on Beaudoin I Table 19, entitled "Optimal Conditions for Lipid Extraction of Aquatic Animal Tissues (suggested procedure)". The Board found that instead of providing for a heating step, this "suggested procedure" for lipid extraction "suggests the use of an organic solvent resistant filter for the filtration step of the process." Appx0019-20; Appx0747. The Board fundamentally misconstrued Table 19 in two respects.

First, the Board erred in concluding that the absence of the heating step from Table 19 means that it is not part of the Beaudoin I process. Table 19 contains only a short, bullet-point summary of the "optimal" extraction method.

As Appellants' expert Dr. Brenna acknowledged, this summary does not provide "a specific protocol, step-by-step protocol." Appx6250-6251, 58:15-59:19; *see also* Appx6231, 39:15-16. One of skill would therefore have to refer to other parts of the written description to determine how to practice Beaudoin I's method. Appx7757, ¶55.

As Appellants' expert Dr. Budge agreed, the written description makes clear that the heating step is a necessary part of Beaudoin I's process. Dr. Budge testified unequivocally that the "postextraction heating step is required" "[t]o produce the final product described in the Beaudoin patent":

> Q. In order to obtain the Fraction I that is disclosed in the Beaudoin patents, would one understand that the heating step needs to be performed?
>
> A. To produce the final product described in the Beaudoin patent, yes, I believe that that postextraction heating step is required.
>
> Q. Why do you say that the postextraction heating step is required to produce the final product?
>
> A. Because Beaudoin mentions heating it, heating the oil.
>
> A. Yeah. Beaudoin has suggested—or I guess teaches us—to perform these heat treatments to remove traces of organic solvent.

Appx6919-6920, 90:1-19, 91:3-15[3]. Neptune's expert Dr. Jaczynski concurred with Dr. Budge's analysis. Appx7757-7758, ¶¶55-56.

[3] In deposition, two of Appellants' other experts, Dr. Brenna and Mr. Haugsgjerd, also abandoned their declaration testimony that the heating step in Beaudoin I is only to prepare the extracts for laboratory analysis. *See* Appx6261-6262, 69:20-70:9, Appx6264, 72:16-21; Appx6275, 83:4-13 (Dr. Brenna characterizing solvent

The Beaudoin I inventors' contemporaneous patent applications and lab notebooks further confirm that they used high heat (up to 130°C) as a mandatory part of their process to remove solvent. Appx7759-7760, ¶59; Appx7036-7038; Appx7759-7760, ¶59; Appx5714, Appx5717-5719, Appx5739. The Board ignored this evidence, as well as Dr. Budge's admission that the heating step is required.

Second, the Board's finding that Beaudoin I teaches removal of toxic solvents through the filtration step listed in Table 19, rather than through the heating step, is fundamentally wrong. Filtration is a well-known technique for separating solid particles from a liquid solution; it is not a process for removing toxic solvents. The reference in Table 19 to filtration using an "organic solvent resistant filter" simply means that the lipid fractions in the extract are separated from solid material using a filter that will not degrade in the presence of organic solvents. As stated in the "Detailed Description of the Preferred Embodiment" in Beaudoin I:

> The solubilized lipid fractions are separated from the solid material by standard techniques including, for example, filtration, centrifugation or sedimentation. Filtration is preferably used.
>
> After separation by filtration on an organic solvent resistant filter (metal, glass or paper) the residue is optionally washed with pure

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removal as an alternative purpose of the heating step); Appx6088-6089, 176:12-177:1 (Mr. Haugsgjerd admitting he does not know "why [Beaudoin I] wrote what he did" regarding heating to 125°C and so "cannot tell you anything about [Beaudoin I's] intentions or…ideas." .

> acetone, preferably two volumes (original volume of material) to recover yet more lipids.

Appx0725. The Board overlooked this disclosure and completely misapprehended the filtration step listed in Table 19.

In sum, Beaudoin I's disclosure, the testimony of both sides' experts, and additional extrinsic evidence ignored by the Board establish that the heating step is a required part of Beaudoin I's process. This is important because established scientific literature demonstrates that the heating step would result in both heat-induced and acid-induced hydrolysis of phospholipids due to the high level of water and free fatty acids in Beaudoin I's extracts, as disclosed in Tables 13 and 14 of Beaudoin I. Appx0741, Appx0742; Appx7735-39, ¶¶13-18, Appx7761, ¶61. Hydrolysis will occur after the heating begins while the oil temperature climbs to 125°C. Appx7738-7739, ¶18; Appx7812. And the heating step will also oxidize fatty acids, especially EPA and DHA. Appx7761, ¶62; Appx6733, 200:2-9; Appx5384.

For purposes of inherent anticipation, one must consider whether Beaudoin I's process, including the heating step, would ***necessarily*** result in a krill extract that contains the claimed phospholipid. *In re Armodafinil Patent Litig.*, 939 F. Supp. 2d 456, 465 (D. Del. 2013) ("if the teachings of the prior art ***can be practiced*** in a way that yields a product lacking the allegedly inherent property, the prior art in question does not inherently anticipate") (emphasis added).

C. The Board Erred in Concluding that the Beaudoin I Extracts Inherently Comprise the Claimed Phospholipid

Based on its erroneous determination that the Beaudoin I process does not include the heating step, the Board summarily dismissed as irrelevant all of Neptune's arguments about the errors committed by Appellants' experts in their "recreations", and then concluded, without any analysis, that "[t]he preponderance of evidence on the record suggests that the *E. pacifica* krill extracts disclosed in Beaudoin [I] necessarily contained the claimed phospholipids." Appx0020. The Board's finding is not based on substantial evidence, and it is contrary to controlling law on inherency.

1. Appellants' experts failed to recreate the Beaudoin I process

Appellants' recreations suffered from a catalog of infirmities, including (1) deviations that rendered the extracted oil less susceptible to hydrolysis; (2) failure to detect, or in some cases, test for the claimed phospholipid; and (3) failure to test for water or free fatty acid concentration as required to prove that the recreation samples were similar to Beaudoin I's extracts.

Prior art recreations that deviate from the reference do not prove inherent anticipation. *See Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 680 (D. Del. 2012) ("[expert] did not accurately reproduce the reaction … [c]onsequently, the court concludes that [expert]'s detection of [molecule] during

his reaction is not reliable to establish inherent anticipation"). Given the known deviations and unreliability of Appellants' recreations, as further detailed below, analyses of the recreation samples do not prove any inherent qualities of Beaudoin I's krill extracts. Appellants therefore failed to prove by preponderance of the evidence that Beaudoin I inherently anticipates the claimed phospholipid (or any other claim elements).

Appellants commissioned and relied on the following "recreations":

	Date	**Extraction By**	**Oil Tested By**
"Haugsgjerd I"	**Oct. 2011**	Mr. Haugsgjerd	Dr. Gundersen
"Haugsgjerd II"	**Apr. 2012**	Mr. Haugsgjerd	**Dr. van Breemen**
"Budge Recreation"	**Sept. 2013**	Dr. Budge	Dr. van Breemen

All three recreations deviated from Beaudoin I in ways that rendered the extracted oil less susceptible to hydrolysis as a result of the heating step, thereby increasing the likelihood that analysis would detect intact phospholipids (including claimed phospholipids) in the post-heated oil.

Haugsgjerd I. The oil samples extracted by Mr. Haugsgjerd were sent to another expert, Dr. Gundersen, for application of the heating step and testing. Dr. Gundersen did not properly apply the heating step. He used ineffective convection heating, placing the samples on a heat block rather than in a water or oil bath as

done in Haugsgjerd II and the Budge Recreation. Appx7751, ¶46. Applying a milder heat treatment than Beaudoin I rendered the oil less susceptible to hydrolysis upon heating.

Haugsgjerd II. Mr. Haugsgjerd added water removal steps during the oil-water separation phase of the extraction. Beaudoin I does not suggest using tools for oil-water separation and describes the step passively (*i.e.*, the water "is allowed" to separate). Appx0725. One would repeat this step by letting the oil and water mixture spontaneously separate on its own and removing the water phase when it appears. Appx7751, ¶47.

Mr. Haugsgjerd, however, used a separatory funnel. Appx6108, 196:3-17. As he admitted, the separatory funnel facilitated removal of water. Reducing the amount of water made the oil less susceptible to hydrolysis. Appx7752, ¶48.

Aker requested that Mr. Haugsgjerd perform the heating step in this second recreation after Dr. Gundersen improperly applied convection heating in the Haugsgjerd I experiment. However, Mr. Haugsgjerd also improperly performed the heating step. He did not monitor the temperature of the oil samples during heating to determine if and when they reached 125°C. Appx6061-6062, 149:14-150:3. There is no proof that these samples were actually heated to 125°C for 15 minutes as Beaudoin I requires. Appx6909, 80:9-15 (Dr. Budge testifying, "how would you ever tell temperature without measuring it?").

Budge Recreation. Dr. Budge also added significant water removal methods, including the use of a separatory funnel and a centrifugation technique. Appx1548, ¶8(5). As discussed above, Beaudoin I teaches letting the oil and water separate on their own. Dr. Budge's deviations would significantly lower the concentration of water in the samples, making them less susceptible to hydrolysis. Appx7753-7754, ¶¶50-51.

All of these recreations thus added important steps or otherwise significantly deviated from Beaudoin I's "explicitly explicated limitations." *See Eli Lily and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001) ("[a] reference includes an inherent characteristic if that characteristic is the 'natural result' flowing from the reference's explicitly explicated limitations"). They therefore do not prove that the claimed phospholipid (or any other element) is a "natural result" inherently flowing from Beaudoin I's process.

2. Appellants' Recreation Data Refutes Inherent Anticipation by Beaudoin I of Claims 1 and 24

The Board's finding that "[t]he preponderance of evidence on the record ***suggests*** that the *E. pacifica* krill extracts disclosed in Beaudoin [I] necessarily contained the claimed phospholipids" (Appx0020) (emphasis added) cannot be squared with Appellants' highly variant recreation data or the law on inherent anticipation, and it should be reversed.

In the Haugsgjerd I recreation, Dr. Gundersen, despite using highly sensitive instrumentation, failed to detect the claimed phospholipid in all of the *E. Pacifica* samples, which comprised ***25%*** of the total number of samples in that recreation. Appx2068-2069; Appx2069; Appx7755-7756, ¶53. These results alone refute inherency. *See Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995) (inherency not proven where experts reproduced prior art method "thirteen times and each time they made [the claimed] crystals," because others twice produced different crystals from the same method). Moreover, in Dr. Budge's recreation, Appellants cherry-picked which samples would be tested for presence of the claimed phospholipid, discarding a full ***one-third*** of the samples based on preliminary tests that showed low phospholipid concentration. Appx1956; Appx1366-1367, ¶¶57-58. Clearly, Appellants were not confident that all recreation samples would "necessarily" contain the claimed phospholipid.[4] On this record, Appellants failed to prove that practicing Beaudoin I's method ***necessarily*** results in a krill extract that contains the claimed phospholipid. *In re Armodafinil Patent Litig.*, 939 F. Supp. 2d at 465 ("if the teachings of the prior art ***can be practiced*** in a way that yields a product lacking the allegedly inherent property, the prior art in question does not inherently anticipate") (emphasis added).

[4] Dr. Brenna characterized this one-third of the Budge samples as "anomalous" and admitted he did not know why they had such a low phospholipid concentration. Appx1629, ¶84 n.4; Appx6340, 148:11-19.

D. The Board's conclusion that Beaudoin I discloses krill extracts suitable for human consumption is not based on substantial evidence

Even if the Board's inherency determination with respect to the claimed phospholipid were correct, its findings of anticipation should still be reversed because Beaudoin I does not disclose an extract suitable for human consumption, under the proper construction of that claim term.

Beaudoin I Table 13 shows that the krill fractions I and II had high moisture and solvent levels, 10.0 and 6.8%, respectively, after evaporation. Appx0741 (Table 13); Appx7762, ¶64. In contrast, the claimed krill extract contains low levels of residual solvent and water. The '351 patent discloses a krill extract containing less than 25 ppm (*i.e.*, less than 0.0025%) of residual solvent. Beaudoin I's extracts contain far too much water and volatiles to be suitable for human consumption. Appx7762, ¶64.[5]

Furthermore, there is no evidence that Beaudoin I's heating step would remove enough water, solvent, and volatile matter to render the extract suitable for human consumption. Appellants failed to test any of the recreation samples for the amount of water, solvent, or volatile matter that the post-heated oil contained. In addition, photographs of some of the Budge Recreation samples appear to contain

[5] In addition, relevant extrinsic evidence such as FDA Generally Recognized as Safe (GRAS) standards for krill oil products further show the unsuitability for Beaudoin I's extracts for human consumption. Appx7762-7763, ¶65.

an unacceptably high amount of water as well as wax and other contaminants. Appx7764, ¶67; Appx7695; *see also* Appx7696-7697, Appx6873-6874, 44:19-45:3.

Beaudoin I acknowledges that the levels of water and solvent in Table 13 are too high by stressing that "it is important" to heat to remove additional solvent. Appx0726, Appx0729. Beaudoin I further emphasizes this point by stating that the "quantity of residual acetone in the water-oil solution after acetone evaporation . . . varies from an experiment to another," and that evaporation would have to be "optimized" at an "industrial scale" (Appx0727), thereby acknowledging that solvent removal was an unresolved challenge. Beaudoin I's lab notebooks further confirm the unsuitability of Beaudoin I's oil for human consumption, as extracts heated even longer than 15 minutes were noted to contain high levels of solvent, such as 7.86%. Appx5753; Appx7763-7764, ¶66.

The Board did not directly address this evidence, instead relying on its erroneous construction of "suitable for human consumption" and the vague statement in Beaudoin I that Dr. Beaudoin "has ingested the different lipid factions of krill" and "[n]o side effect profile was observed." Appx0731. A person of ordinary skill would not view such an anecdotal report of a single ingestion or tasting of an undisclosed amount of oil as proof of suitability for human consumption. Appx7765-7766, ¶¶68-69. As Dr. Brenna admitted: "No, I don't think it's safe [to consume a krill oil] containing an unknown amount of residual solvent." Appx5497-5498, 112:9-113:1. In other words, tasting an extract containing a toxic level of solvent shows recklessness, not fitness for human consumption. As already shown herein, the '351 patent teaches that suitability for human consumption entails human ingestion on a repeated or regular basis, as in the case of a dietary supplement like a krill oil capsule.

Because Beaudoin I does not expressly or inherently disclose an extract that is safe and appropriate for humans to ingest, this Court should reverse the Board's anticipation findings.

III. THE BOARD ERRED IN FINDING OBVIOUSNESS OF 24 CLAIMS BY THE COMBINATION OF FRICKE, BERGELSON, YASAWA, ITANO, AND THE WHO BULLETIN

The Board concluded that the five-way combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin renders obvious claims 1-4, 6, 12, 13, 19-27,

29, 35, 36, and 42-46 of the '351 patent. These findings are unsupported by these disparate references and the law. When properly evaluated, Appellants' references, whether alone or in combination, do not teach or suggest a krill extract comprising the claimed phospholipids that is suitable for human consumption.

A. The Board Erred in Finding a Motivation to Combine

1. Appellants' Cherry-Picked References are Focused on Very Different Subjects and Applications

To prove obviousness based on more than one reference, one must show that (1) a person of ordinary skill in the art would have been motivated to combine the references, and (2) there would have been a reasonable expectation of successfully achieving the claimed invention from such combination. *See Leo Pharma. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1355-57 (Fed. Cir. 2013); *see also In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) ("courts should not succumb to hindsight claims of obviousness").

Furthermore, secondary considerations, such as prior art that teaches away from the claimed inventions, "can be the most probative evidence of nonobviousness" and are useful to "avert the trap of hindsight.'" *Leo Pharma.*, 726 F.3d at 1358 (internal citation omitted). The M.P.E.P. is in accord. M.P.E.P. § 2141.02 specifies that in an obviousness analysis, "[a] prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention." In addition, in reaching a conclusion of obviousness,

"impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." *See* M.P.E.P. § 2142.

The Board's decision summarily stated that "Itano and WHO Bulletin recognize krill as valuable for human consumption and thus provide a reason to modify the extracts disclosed in Fricke for human consumption." Appx0028. But the Board failed to consider the references in their entirety, including why a person of skill in the art would have brought these five references together in the first place, given the crucial differences in their objectives.

The erroneous conclusion that one of skill in the art would be motivated to combine Appellants' references infects each of the Board's obviousness determinations. These five references, spanning 15 years, are focused on disparate issues that do not suggest combination.

Fricke, published 17 years before the '351 Patent's priority date, is an academic study whose sole purpose is to investigate the lipid composition of krill. Appx0860-868. Fricke uses a basic Folch extraction, which all parties recognize involves dissolving the lipids in toxic solvents (methanol and chloroform). Such an extraction is perfectly reasonable for the academic purposes of Fricke's investigation; the lipid extracts in Fricke exist for no other reason than to determine what lipids are in live krill. Notably absent from Fricke's analysis of krill is any mention whatsoever of what a ***krill extract*** might be used for, let alone any

suggestion that a krill extract could or should be made suitable for human consumption.

Bergelson, Appellants' other primary reference, is also an academic publication – a chapter of the textbook *Lipid Biochemical Preparations*. Bergelson published in 1980, over twenty years before the '351 Patent's priority date. Like Fricke, Bergelson is also directed to preparation of extracts for laboratory analysis using methanol and chloroform, and does not teach or suggest any way to remove the toxic solvent to render extracts suitable for human consumption. To the contrary, Bergelson teaches adding an additional toxic substance and known carcinogen, benzene, to aid in solvent removal. Appx1058. Unlike Fricke, Bergelson is silent with respect to krill and marine extraction material generally. Bergelson actually disclaims use of its methods on "exotic starting materials" such as krill, and thus teaches away from the claimed krill extracts. Appx1042; Appx7773-7774, ¶¶86-87.

Yasawa, a Japanese patent application published in 1996, does not disclose any krill extract comprising the claimed phospholipid or any methods for extracting phospholipids from krill. Yasawa discloses the administration of DHA for improving dementia symptoms (but is silent as to EPA), and does not distinguish between the source of the DHA. Appx1002, Abstract; Appx1003,

¶[0008]. Thus, Yasawa contains no teachings relevant to the claimed krill lipid extracts.

Itano is an advertising pamphlet "announcement" containing vague, cursory descriptions of krill-derived food products. It contains no technical information whatsoever, and does not teach how to make the advertised products or the claimed krill extracts. Appx7781, ¶102; Appx6423, 231:11-22.

The WHO Bulletin is a one-page excerpt of a 1995 World Health Organization (WHO) newsletter that discusses potential nutritional benefits of consuming ***krill meat***. It does not teach or suggest preparation of any ***krill extract***, let alone a krill lipid extract.

2. One of Skill Would Not Combine Fricke or Bergelson with Yasawa, Itano, or the WHO Bulletin

One skilled in the art would not look to Fricke or Bergelson to obtain an extract suitable for human consumption because, as detailed above, these references teach a method that produces a toxic lipid extract. The toxicity of Fricke's and Bergelson's extracts is unremarkable because these are academic references teaching preparation of lipid samples for laboratory analysis. But such toxic extracts are incompatible with the teachings of Yasawa, Itano, and the WHO Bulletin, which relate to human ingestion of omega-3 fatty acids, krill-derived food products, or krill meat. A skilled person simply would not combine the teachings of Fricke and Bergelson with that of Yasawa, Itano, or the WHO Bulletin, as they

are directed to drastically different purposes, *i.e.*, analytical lipidology versus human consumption. Appx7776, ¶91.

3. Appellants' Combination Includes Krill and Non-Krill References That A Person of Skill Would Not Combine

A person skilled in the art would have no motivation to combine Bergelson or Yasawa with Fricke, Itano, and/or the WHO Bulletin to arrive at a krill extract. Bergelson is silent about krill or other marine species, teaching that its procedures are for "organs of rats or cattle, common vegetables, cereals and some readily available microorganisms," and disclaiming the use of its methods on "exotic starting materials." Appx1040. A person skilled in the art would have deemed krill an "exotic starting material" in 2001 or 2002.

Appellants' other art demonstrates this point. For example, the Suzuki article notes that in Japan, which was at the forefront of krill utilization, krill was not a common product as of 1990. Appx1033. In 1995, the WHO Bulletin characterized krill-derived products as "represent[ing] novel areas for research." Appx1068. As recently as 2005 (four years *after* the priority date of the '351 patent), the industry literature designated krill as a "non-conventional species" and noted that "[i]mproved technology would be needed to catch and process" krill "into acceptable edible products." Appx5139-5140. Therefore, one of skill would not have looked to Bergelson for teachings related to krill lipid extraction. Appx7773-7774, ¶86.

A person of skill would also not be motivated to obtain a krill extract based on Yasawa. Appx7777-7778, ¶95; *see also* Appx7778-7780, ¶¶96-100. As discussed above, Yasawa concerns the administration of DHA, and does not disclose any krill extract comprising the claimed phospholipid or any methods for extracting phospholipids from krill. Furthermore, Yasawa discloses that DHA is equally valuable regardless of which of many possible sources it is derived from, such as numerous types of fish, dolphins, or microorganisms. Appx1003, ¶[0008]. Yasawa does not recognize that krill extracts offer DHA and EPA primarily esterified in phospholipids, while other natural sources of omega-3s, such as fish oil, contain DHA and EPA bound to triglycerides. It is precisely this structural difference that confers the enhanced bioavailability of DHA and EPA derived from krill oil as opposed to from other sources. Appx7733-7734, ¶¶10-11; Appx7026.

Accordingly, Yasawa does not direct one to choose krill as a source of DHA instead of fish or any other source. To the extent Yasawa would motivate a person of skill in the art to extract DHA from a natural source, a person of skill acting in 2001 or 2002 would have chosen fish, not krill. Appx7780, ¶100. *See* M.P.E.P. § 2145 ("[W]here the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful," the invention is non-obvious). At the time of Dr. Sampalis' invention, the industrial infrastructure and state of the art for fish oil extraction was highly

developed, whereas krill was difficult and expensive to obtain and process, and little was known about how to extract krill oil for commercial use. Appx7777-7778, ¶95; Appx7780, ¶100.

4. One of Skill Would Not Combine Itano With Lipid Extraction References

A person of skill in the art would not combine Itano with Fricke or Bergelson. As discussed above, Itano is an advertisement entirely devoid of technical information. It does not teach how to make the advertised products or the claimed krill extracts. Appx7781, ¶102; Appx6423, 231:11-22. Nor is there any evidence that the advertised products in Itano ever existed.

Itano describes a protein product derived from krill, while Fricke and Bergelson teach academic methods for lipid extraction. As detailed below, a person of skill in the art would recognize that obtaining protein from krill and obtaining phospholipids from krill are two conflicting objectives. Appx7782, ¶104.

While Itano has a cursory description of a generic "krill lecithin," Itano focuses on obtaining a krill-derived protein flavoring product called "Eleven One." Appx7781-7782, ¶103. For example, Itano emphasizes that krill "is a valuable source of protein," and that "high quality" protein is "[t]he main component" of krill. Appx0888; Appx0890. Itano's claims regarding health benefits, such as

"checking high blood pressure," are based on the protein components (*i.e.*, the tripeptides) of the extracts.

Phospholipids are undesirable contaminants in a protein product such as that suggested by Itano because when phospholipids are co-extracted with protein, the phospholipids will cause increased hydrolytic and oxidative rancidity. As a result, a protein product containing a high amount of phospholipids would have a shorter shelf life and an offensive, fishy odor. Therefore, Itano's stated goal of obtaining a protein-rich product from krill *teaches away* from a krill extract containing significant phospholipids. Appx7782, ¶104; *see also id.* ¶105.

The production flow chart in Itano further teaches away from the claimed krill extracts because: (1) it shows no extraction performed with organic solvent, as would be required to yield significant concentrations of phospholipids potentially safe for human consumption; and (2) it ends with a "heat sterilization" step, which indicates a lack of interest in preserving phospholipids and omega-3 fatty acids. Appx7781-7782, ¶103; Appx0894.

B. The Board Erred in Concluding that It Would Have Been Obvious to Convert Toxic Extractions Made for Analytical Purposes into Krill Extracts Suitable for Human Consumption

None of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin, alone or in combination, teach or suggest a krill extract suitable for human consumption.

Neither Fricke nor Bergelson teaches or suggests any way to sufficiently remove the toxic chloroform and methanol solvents to render the extracts suitable for human consumption. Appx7772-7775, ¶¶84, 88; *see also* Appx6612-6614, 79:18-81:5 (chloroform is toxic and must be removed "as much as possible" from an extract intended for human consumption). Bergelson in fact warns of the toxicity and danger associated with chloroform and methanol exposure. Appx1053.

The Board relied on Bergelson's teaching of solvent removal by rotary evaporation. Appx0028. But while evaporation may be used to remove most solvents, Bergelson is focused on laboratory analysis and does not suggest sufficient removal of toxic solvents during evaporation so as to render an extract suitable for human consumption. To the contrary, Bergelson teaches adding an additional toxic substance, the known carcinogen benzene, to facilitate evaporation. Appx1058. Benzene is poisonous and unsafe to ingest. Appx7537-7541; Appx7775, ¶89. Accordingly, neither Bergelson nor Fricke teaches any method for preparing an extract suitable for human consumption, and in fact, each reference teaches away from such an extract by employing toxic solvents for extraction and subsequent rotary evaporation. *E.g.*, Appx7772-7775, ¶¶84, 89.

As this Court recently restated, "precedent requires that the Board explain a rationale why a person of ordinary skill would have modified [the prior art]."

Black & Decker, Inc. v. Positec USA, Inc., Case Nos. 15-1646, -1647, 2016 WL 2898012, at *6 (Fed. Cir. May 18, 2016). Not only is the Board's reasoning erroneous, but Appellants' other prior art definitively shows that it would ***not*** have been obvious to one of skill in the art in 2001 or 2002 to prepare an extract for human consumption using Folch or similar methods that use chloroform and methanol as solvents. For example:

- *Beaudoin I* (published in 2000): teaches that the Folch method "is not commercially feasible because of the toxicity of the solvents." Appx0722; Appx7771, ¶83; *see also* Appx7091 ("[p]rior to the present [Beaudoin I] invention, the only solvents that appeared to produce good results to extract total lipids from krill was a combination of chloroform and methanol. Notably, however, ***these solvents are unacceptable for the food industry....***" because of their toxicity).
- *Maruyama*: teaches that use of chloroform is unacceptable because it "entails the fear that harmful substances might remain, no matter how the [extracts] are refined and fractionated, making it difficult to use this in food products." Appx0814; Appx7771-7772, ¶83.
- *Fujita*: teaches that extracts intended for use in human food products should be obtained with non-toxic organic solvents. Appx0832;

Appx7771-7772, ¶83. Similarly, Mr. Haugsgjerd testified that Norwegian law prohibits the use of chloroform to produce fats and oils that may be used in food. Appx5937-5938, 25:7-26:2.

Neither Appellants nor the Board cited evidence of ***any*** prior art krill extract prepared using chloroform and methanol that is suggested to be suitable for human consumption. *See K/S HIMPP v. Hear-Wear Techs., LLC*, 751 F.3d 1362, 1366 (Fed. Cir. 2014) (in *inter partes* review proceedings, "the Board cannot accept general conclusions . . . as a replacement for documentary evidence for core factual findings…."). Dr. Brenna admitted he knows of no instance in which this has been attempted, let alone successfully done. Appx6403-6408, 211:17-216:21. Dr. Brenna also admitted that decades before the '351 Patent, "the Federal government declared that ***chloroform should be*** as low as possible and ***avoided when other solvents could be used*** and that sort of thing." Appx6418, 226:6-16 (emphasis added). These admissions are fatal to the Board's conclusion that it would have been obvious to a person of skill that a Folch krill extract could, with a reasonable expectation of success, be processed to be suitable for human consumption.[6]

[6] The Board relied on Appellants' arguments concerning an FDA guidance document. Appx0029; Appx3592. There are numerous problems with Appellants' and the Board's use of this document. First, Appellants did not rely on it in their petitions, failed to produce it in discovery, and first disclosed it at the deposition of Neptune's expert. Second, Appellants chose not to have their own experts rely on this document or opine on it in any way, and no expert testimony has established its relevance. Third, the guidance in this document is inconsistent with the

Even if "suitable for human consumption" is interpreted to require suitability only for topical use, Fricke and Bergelson still would not teach or suggest an extract that satisfies independent claim 24 and its dependents, which require an oral preparation comprising the claimed extract. One of skill would therefore understand claim 24 to require an extract that is safe for oral ingestion. Appx7776, ¶92. Fricke and Bergelson do not teach or suggest a krill extract safe for oral ingestion at least because they use toxic solvents and disclose no method for sufficiently removing them from the extract.

Moreover, Yasawa, Itano, and the WHO Bulletin contain no teachings regarding removal of chloroform and methanol from a lipid extract. These references actually do not disclose anything regarding solvent removal from a lipid extract. Thus, they add nothing to Fricke and Bergelson with respect to suitability for human consumption.

Accordingly, the Board erred in finding that this combination of prior art renders obvious a krill extract that is suitable for human consumption.

The combination also does not teach or suggest the other elements that comprise every claim at issue. It is undisputed that none of the five references discloses a phospholipid containing DHA and/or EPA at both fatty acid positions,

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"Generally Recognized as Safe" (GRAS) data for the parties' products, which allow for far lower levels of residual solvents (Appx4840; Appx4930; Appx5009) compared to the FDA guidance document (Appx3600).

and Appellants and the Board point only to Fricke as disclosing anything relevant to the claimed phospholipid. Appx0027-28. In finding that the claimed phospholipid would be present in Fricke, the Board relied on the same flawed analysis of the "recreations" discussed above regarding inherent anticipation. *Id.* Appellants also relied on an analysis of Fricke ***that required the context of the '351 patent*** (Appx5602-5603 at 217:18-218:8; *accord* Appx7769, ¶79), and a paper that ***published about eight years after the '351 patent's priority date***, which used an extraction method different than Fricke's. Appx0993-0999; Appx6349, 157:3-19, Appx6352, 160:14-18, Appx6353, 161:12-14; Appx7769-7770, ¶80. These arguments represent the epitome of impermissible hindsight reconstruction. As for "krill extract," Bergelson is silent with respect to krill and marine extraction generally, and disclaims the use of its methods with "exotic starting materials," which would describe krill at all relevant times. The WHO Bulletin concerns eating ***krill meat***, and has nothing to do with krill extracts.

C. The Board Erred in Finding Claims 2, 3, 25, and 26 Obvious Over the Asserted Combination

Claims 2, 3, 25, and 26 further require that the claimed krill extract have a ***total phospholipid concentration*** that falls within specified ranges. Claims 2 and 25 require a phospholipid concentration of about 40% w/w of the extract, wherein about represents ±10%. Claims 3 and 26 require a phospholipid concentration of about 45% w/w of the extract, wherein about represents ±20%. These features are

also not disclosed in Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin, alone or in combination.

The Board erroneously concluded that Fricke Table 1 discloses a phospholipid concentration that satisfies claims 2, 3, 25, and 26. Appx0030-31. As stated in Fricke, and as admitted by Dr. Brenna, Table 1 shows phospholipids as a "wt % of total lipids", not as wt % of total extracts as claims 2, 3, 25, and 26 require. Appx0863; Appx6370-6371, 178:18-179:18; Appx7784, ¶110. Fricke Table 1 does not disclose what percent of the weight of the extract phospholipids comprise, the feature relevant to claims 2, 3, 25, and 26.

Dr. Brenna nevertheless asserted that one can rely on Table 1 to establish phospholipid concentration because in a Folch extraction, "the total lipids and the lipids of the extract are essentially coincident." Appx6372, 180:1-18. According to Dr. Brenna, one of skill would assume that in a Folch extract, "99 percent of it, nearly a hundred percent of it," is lipids, with only "trace levels" of non-lipid components. Appx6373-6374, 181:14-182:11.

Dr. Brenna is wrong. One of skill would not assume that a Folch krill extract would be 99% or more lipids. Appx7784-7786, ¶¶112-115. For example, a study published by Mr. Haugsgjerd shows that krill extracts obtained using the Bligh & Dyer method (which is analogous to Folch because it also employs chloroform and methanol as solvents), had total lipid concentrations as low as 92.3

and 90% of the total weight of the extract, meaning that as much as 10%—over ten times Dr. Brenna's estimate—were non-lipid components. Appx7784-7785, ¶112; Appx5212 (Table 3). Bergelson also teaches that in Bligh & Dyer extracts, "some 25-75% of the total mass of the extract may represent non-lipid contaminants," including "mainly aminoacids" and "short peptides." Appx0020; *see also* Appx7785, ¶114.

Furthermore, Dr. Brenna admitted that he did not know how to modify the Folch method described in Fricke to obtain a krill extract that contains the claimed phospholipid concentrations, and indeed, that he had never even considered the issue before declaring these claims to be obvious based on Fricke. Appx6383, 191:12-20. In addition, as discussed above, the Fricke extract would have to somehow be rendered suitable for human consumption—an act that could very well reduce the concentration of phospholipids. Even a small amount of hydrolysis resulting from the efforts to sufficiently remove the toxic solvent would leave the resulting extract with phospholipids below the claimed range.

The secondary references in this combination contain no teachings relevant to obtaining a krill extract with the required phospholipid concentrations of claims 2, 3, 25, or 26, (Appx7786, ¶115), and neither the Board nor Appellants stated otherwise. Accordingly, claims 2, 3, 25, and 26 are not obvious in view of the Fricke, alone or in the proposed combination.

IV. THE BOARD'S DETERMINATION THAT APPELLANTS FAILED TO PROVE OBVIOUSNESS OF CLAIMS 5 AND 28 IS BASED ON SUBSTANTIAL EVIDENCE

Claims 5 and 28 require a concentration of free fatty acids ("FFAs") of "about 5% w/w of the lipids" in the recited krill extract. Supported by the finding that "the Fricke extracts having free fatty acid concentrations of 8.5% to 16.1% [are] outside the claimed range," the Board concluded that Appellants failed to prove obviousness of Claims 5 and 28. Appx0032. The Board's conclusion is supported by substantial evidence.

A. The Board Correctly Construed the Term "About 5%"

The specification provides that when "about" is used with a stated numerical value, the value may vary by at least ± 50%, unless another range for "about" is otherwise specified, such as in claims 2 and 25 ("wherein about represents ± 10%"). Appx0064, col. 21:62-64. As claims 5 and 28 do not provide a particular plus or minus percentage for "about," one would understand based on the specification that claims 5 and 28 require a concentration of free fatty acids of plus or minus 50% of 5%, *i.e.*, a range of 2.5% (5% minus 2.5%) to 7.5% (5% plus 2.5%). Appx7746-7747, ¶37.

In their zeal to sweep in prior art, Appellants argue that one of skill would understand 5% ± 50% to cover a range that is 5% plus or minus an *absolute value* of 50%. In other words, 50% must be subtracted from and added to 5%. Under

that reasoning, the claimed range would be -45% to 55% free fatty acid, which is nonsensical because an extract cannot have a negative amount of free fatty acids.[7] Appellants attempt to salvage their untenable interpretation by asserting that the bottom end of the range should be cut off at 0%, because the patent claims "can only sensibly be understood to refer to amounts between 0 and 100%." Appellants' Br., 32. This is pure sophistry. If the applicants had intended to cover a range of 0% to 55% free fatty acid concentration, they would have stated that range explicitly, rather than using a phrase meaning 5% plus or minus an absolute value of 50%.

Appellants' construction allowing up to 55% free fatty acid concentration is also contrary to the teachings of the '351 patent. Low levels of free fatty acids, *i.e.*, 2.5-7.5%, indicate that phospholipids have not undergone substantial hydrolysis. A low free fatty acid level is consistent with a core teaching of the '351 patent, namely, recovery of intact phospholipids in a krill extract. A high free fatty acid level, on the other hand, would indicate that the phospholipids have degraded and the extract is less desirable. Appx7746-7747, ¶37.

Appellants assert, without explanation or supporting evidence, that it "makes no sense" for the range of variation to increase as the stated concentration increases, and that the Board's construction is unreasonable because it requires

[7] In the ITC Action, Dr. Brenna opined that "about 5%" covered ***any amount*** of free fatty acids, *i.e.*, 0% to 100%. Appx5413-5417, 28:10-32:14.

"the public to work through two equations (multiply 50% times 5%, then add (and subtract) the resulting value to (and from) 5%) just to determine a claimed range [the applicants] could have simply said." Appellants' Br., 29-30. During the ITC Action, however, Appellants had no such concerns in proffering their constructions of "about . . . plus or minus" in claims 2 and 3 (and claims 25 and 26). Claim 2 recites, "the extract has a total phospholipid concentration in an amount of about 40% w/w, wherein about represents ± 10%", while claim 3 states, "the extract has a total phospholipid concentration in an amount of about 45% w/w, wherein about represents ± 20%". Instead of arguing that 10% and 20% should be subtracted from and added to the stated phospholipid concentration percentages, Appellants adopted the same approach that they now lambast. Specifically, Appellants agreed that 10% and 20% must be multiplied against the concentration percentages, with the resulting value being added to and subtracted from the concentration percentages, resulting in claimed ranges of 36%-44% (claims 2 and 25) and 36%-54% (claims 3 and 26). Appx0379-380.

In a transparent attempt to bolster their proposed construction for claims 5 and 28, Appellants flip-flopped before the Board, arguing for constructions of 30%-50% and 25%-65%, respectively, for the phospholipid concentration claims. Appx0632. Dr. Brenna, however, admitted that when he prepared his declaration for Aker's IPR petition, he interpreted claim 2 to require a phospholipid

concentration of 36%-44%, just as he and Appellants had done in the ITC Action. Appx0379 (citing Appx6328, 136:6-14). The Board ultimately rejected Appellants' changed constructions and adopted the constructions for the phospholipid concentration claims to which the parties had agreed in the ITC Action. Appx0012.

There is no principled basis for construing "about . . . plus or minus percent" one way for claims 2, 3, 25 and 26, and a completely different way for claims 5 and 28. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005) ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims."). Appellants' interpretation of "plus or minus 50%" in claims 5 and 28 is unreasonably broad. The Board properly rejected it, and its construction should be affirmed.

B. Appellants' Obviousness Argument Relied Solely on the Free Fatty Acid Concentrations Purportedly Disclosed in Fricke, which Are Not in the Claimed Range

Appellants argue that the Board "misapplied the test for obviousness in a manner resembling anticipation." Appellants' Br., 39. But Appellants failed to make any obviousness argument for Claims 5 and 28 beyond the mere reference to the values stated in Fricke. As already shown, with respect to all claims, Appellants failed to identify a reason why or how one of skill in the art would seek

to convert the Fricke extracts into ones suitable for human consumption. In fact, Appellants' references taught away from such an attempt, since one would avoid using toxic solvents when making a product for human consumption. *See supra* Section III.B.

Appellants' failure of proof is even more glaring when it comes to the specific limitations of Claims 5 and 28. There is simply nothing in Fricke or any of the other obviousness references that would suggest to one skilled in the art that FFAs should be within the claimed range, nor any teaching as to how to ensure that FFAs are kept within the claimed range when removing the toxic solvents from the Fricke extracts so as to render them suitable for human consumption. In the absence of any guidance regarding concentration of FFAs, let alone any broader motivation to render the Fricke extracts suitable for human consumption, Appellants could not (and did not) make any attempt to show how it would have been obvious to one skilled in the art to create an extract suitable for human consumption with FFAs in the claimed range. As a result, Appellants' obviousness argument is really nothing more than a faulty anticipation argument. In concluding that Appellants failed to prove obviousness of Claims 5 and 28, the Board only addressed the disclosure of Fricke, because that disclosure is the sum total of Appellants' obviousness argument.

Fricke does not provide the asserted disclosure on which Appellants' obviousness argument depends. Appellants argue that, "[o]n its face, Fricke discloses an extract with '8.5 +/- 1.0' percent free fatty acids." Appellants' Br., 39. Fricke does no such thing. First, the reference disclaims the very data on which Appellants rely. Specifically, Fricke's Table 1 includes an important caveat not addressed by Appellants. Footnote a—which applies ***only*** to the FFA values—notes that the measurements are "probably mostly artifacts." Appx0863 (Table 1, footnote a). An artifact is an observation not naturally present, but rather a result of the preparative or investigative procedure. As Neptune's expert testified, a measured value "may turn out to be an artifact, not a true difference." A3443-3444, 150:1-2.

Not only did the Fricke authors specifically note that the FFA measurements are "probably mostly artifacts," but the unreliability of these measurements is highlighted by the large standard deviation associated with the values. The +/- 1.3 and +/- 1.0 standard deviations for the FFA values in Table 1 far exceed any other standard deviations in the table. Appx0863 (Table 1). Appellants now seek to use that very unreliability to their advantage by applying the large standard deviation associated with the already suspect 8.5% value to arrive at 7.5%, thereby abutting the upper limit of the claimed 2.5%–7.5% range.

Perhaps recognizing that this argument strains credulity, Appellants did not even raise it at trial; neither Appellants' oral argument nor their demonstratives made any reference to the standard deviations of the disclosed FFA measurements. In fact, Appellants' demonstrative addressing FFA highlighted ***everything but*** the standard deviations:

TABLE 1

Lipid Composition of Antarctic Krill
(*Euphausia superba* Dana)

Sample	12/1977	3/1981
Total lipid content (% wet weight)	2.7 ± 0.2	6.2 ± 0.3
Phospholipids		
Phosphatidylcholine	35.6 ± 0.1	33.3 ± 0.5
Phosphatidylethanolamine	6.1 ± 0.4	5.2 ± 0.5
Lysophosphatidylcholine	1.5 ± 0.2	2.8 ± 0.4
Phosphatidylinositol	0.9 ± 0.1	1.1 ± 0.4
Cardiolipin	1.0 ± 0.4	1.6 ± 0.2
Phosphatidic acid	0.6 ± 0.4	
Neutral lipids		
Triacylglycerols	33.3 ± 0.5	40.4 ± 0.1
Free fatty acids[a]	16.1 ± 1.3	8.5 ± 1.0
Diacylglycerols	1.3 ± 0.1	3.6 ± 0.1
Sterols	1.7 ± 0.1	1.4 ± 0.1
Monoacylglycerols	0.4 ± 0.2	0.9 ± 0.1
Others[b]	0.9 ± 0.1	0.5 ± 0.1
Total	98.9	99.3

Data are expressed as wt % of total lipids and represent means ± standard deviation of 3 separate experiments.

[a] Probably mostly artifacts.

[b] Traces of lysophosphatidylethanolamine, phosphatidylserine, sphingomyelin, glycolipids, sterol esters, waxes and carotenoids were detected.

Appx4700 (highlighting in original).

Instead, Appellants relied on the 8.5% value and argued simply that "[Neptune] ha[s] not explained to you why 8.5 percent free fatty acid levels is going to make any difference as compared to an extract with a 7.5 [percent] free fatty acid level." A0685-686, 72:24-73:1. That argument is irrelevant to the obviousness analysis. Appellants failed to show that Fricke disclosed an extract containing the claimed range of FFAs, and failed to show why one of skill would seek to achieve a particular range of FFAs in either the initial toxic extract or in one that could somehow be rendered suitable for human consumption. Having premised their argument on an express disclosure, Appellants' question of whether there is a difference between the claimed range and the unreliable disclosed value is a red herring.

Appellants note in their brief that they also relied at trial on a statement in Fricke that samples from krill that were handled differently "showed a FFA content which was much lower, ranging from 1% to 3% of total lipids." Appellants' Br., 42-43; Appx0863-864. Fricke provides no other information about these samples—no data or analysis of any kind, no description of an extraction procedure, and no indication that the measurement even came from a krill extract. If the lipids from this sample had been extracted and analyzed, it is reasonable to assume that the Fricke authors would have included the results as another data point in their "thorough and complete analyses" of krill lipids.

Appx0862. Again, presumably recognizing the unreliability of this disclosure, Appellants did not even include this argument in their petitions for IPR. Appx0134, Appx7950.[8]

C. Claims 5 and 28 are not Obvious, Regardless of the Disclosed Concentrations of Free Fatty Acids

Appellants contend that, even if Fricke does not disclose the claimed FFA range, Claims 5 and 28 are nonetheless obvious:

> Even accepting, counterfactually, that Fricke discloses only krill extracts with 8.5-16.1% free fatty acids, it does not teach a person of skill in the art to limit himself to those amounts, and there is no reason to suppose that a person of ordinary skill would restrict himself to those amounts. ***Neither the Board nor Neptune has offered any reason.***

Appellants Br. at 46. (emphasis added).

Appellants turn the burden of proof for obviousness on its head. Neptune need not show that one of skill would limit himself to the FFA range disclosed in

[8] Appellants note that their expert did address the 1-3% disclosure. Appellants' Br., 43. But Dr. Brenna's declaration merely parrots the disclosure without any analysis of its reliability. For example, Dr. Brenna did not address why no other information is provided about this sample (including whether it is a krill extract or simply dried krill). Regarding the FFA disclosures in general, Dr. Brenna did not address the wide variability of the measurements or the fact that they are "probably mostly artifacts." He also did not identify any reason why a person of skill in the art would seek to maintain a concentration of FFA in the claimed range while converting the toxic Fricke extracts into one that is suitable for human consumption, or how one might achieve this. Rather, the ***entirety of Dr. Brenna's opinion regarding FFAs in Fricke*** is the conclusory statement that "[t]he Fricke Article discloses a krill extract that has a concentration of free fatty acids of about 5% w/w of the lipids in the extract, as recited in claim 5 of the '351 patent." Appx1716, ¶285.

Fricke. Rather, Appellants need to show that one of skill would be motivated to create an extract suitable for human consumption that has the claimed range of FFA.

In reversing a recent obviousness finding, this Court explained:

> ***Our precedent requires that the Board explain a rationale why a person of ordinary skill would have modified [the prior art]***. *See Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc.*, 555 F.3d 984, 993 (Fed. Cir. 2009) (explaining that the skilled artisan's motivation "should be made explicit"). In its decision, the Board stated that [the prior art] "suggests" the limitation. *Final Written Decision*, 2015 WL 5440722, at *16. It went on to state what one of skill in the art "would have known" or "could have" done to meet the limitation. *Id.* This is not sufficient. Our precedent required that the Board explain why one of skill in the art would have adapted or replaced [the prior art]….The Board did not do so.

Black & Decker, Inc. v. Positec USA, Inc., Case Nos. 15-1646, -1647, 2016 WL 2898012, at *6 (Fed. Cir. May 18, 2016) (emphasis added). Furthermore Appellants have identified nothing in Fricke or any combination of references that would suggest creating an extract with any particular range of FFA (let alone the claimed range), or provide a reasonable expectation that such a goal could be achieved. As already discussed, Fricke has nothing to do with krill extracts; rather, extraction is only relevant for the purposes of removing the lipids from krill in order to see what they are. Appx0862. Furthermore, Fricke is not concerned with ***any*** uses of krill or krill extracts, let alone any human consumption of krill extracts.

Even assuming *arguendo* that the combination of Fricke with Appellants' other references would lead one to try to modify Fricke's extract to make it suitable for human consumption—and even assuming that such modification would be possible—there is still nothing to suggest modifying the Fricke extract to achieve any particular level of FFAs, nor any suggestion of how to do this. Furthermore, any process used to remove toxic solvent (such as heating), could alter the compositions of the extract in unpredictable ways. The absence of any teaching or motivation to modify the Fricke extract is particularly important with regard to the concentration of FFAs, since, as demonstrated by Fricke itself, the concentration is highly variable and dependent on processing conditions.

V. APPELLANTS' ATTACKS ON THE BOARD'S DENIAL OF THEIR REQUEST FOR REHEARING FAIL

Following issuance of the Final Written Decision, Appellants sought rehearing, arguing that the Board should consider whether Claims 5 and 28 are anticipated by Maruyama and Fujita, two grounds on which IPR was not instituted. A series of opinions by this Court and the Supreme Court (issued after Appellants filed their brief) make clear that the Board's decision was not only within its discretion, but is also non-appealable.

A. The Board's Decisions Concerning Institution are not Reviewable

Most of Appellants' arguments are nearly identical to those repeatedly rejected by this Court. It is "clear that [under § 42.108] the Board may choose to

institute some grounds and not institute others." *Harmonic, Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1368 (Fed. Cir. 2016). And the Board's decisions related to institution of specific grounds are not reviewable. *Cuozzo*, 2016 WL 3369425, at *8-*10; *Harmonic*, 815 F.3d at 11366-68; *HP Inc. v. MPHJ Tech. Investments, LLC*, 817 F.3d 1339, 1344-48 (Fed. Cir. 2016).

Contrary to Appellants' arguments, the prohibition on judicial review is not limited to just decisions to institute IPR. Rather, "§ 314(d) bars [] review of aspects of the institution decision other than the § 314(a) determination whether there is a reasonable likelihood that the petitioner would prevail," *HP*, 817 F.3d at 1345, including barring "review of the decision to institute on only some grounds." *Id*. at 1346. The Supreme Court recently explained why institution decisions are not reviewable:

> The text of the "No Appeal" provision, along with its place in the overall statutory scheme, its role alongside the Administrative Procedure Act, the prior interpretation of similar patent statutes, and Congress' purpose in crafting inter partes review, all point in favor of ***precluding review of the Patent Office's institution decisions***.

Cuozzo, 2016 WL 3369425, at *8 (emphasis added). Furthermore, the bar on review applies to "questions that are closely tied to the application and

interpretation of statutes related to the Patent Office's decision to initiate inter partes review." *Id*.[9]

Although Appellants appear to argue otherwise, there can be no serious contention that the Board's refusal to institute on certain grounds is materially different than the Board's refusal to revisit those same grounds following the final written decision. Both decisions involve the same unreviewable discretion of the Board to consider only some grounds.

Harmonic is dispositive here. In *Harmonic*, the Board instituted on one ground and denied as redundant "four other distinct grounds of unpatentability" of the claims. *Harmonic*, 815 F.3d at 1364. The Board then issued a final written decision invalidating most claims, but upholding others. Harmonic argued "that in light of the Board's conclusion in its final written decision that [the references of the instituted ground] do not render [the upheld claims] unpatentable, the Board was compelled to revisit the grounds it previously deemed redundant." *Id.*

This Court disagreed and concluded that it did not have jurisdiction to review the Board's institution decision. As an initial matter, the Court concluded that the Board's rationale in refusing to consider all grounds did not trigger appellate review:

[9] *Cuozzo* does not bar review where the Board has engaged in "shenanigans," and "arbitrary and capricious" decisions can be set aside. *Cuozzo*, 2016 WL 3369425, at *8. As explained below, however, the Board's decisions here were sound, and do not trigger this exception to the "No Appeal" provision.

> For us to hold that by providing the public with a basis for its institution decision—redundancy—rather than remaining silent, the Board somehow triggered our appellate jurisdiction would violate both § 314(d) and our governing case law.

Id. at 1367. Furthermore, the Court concluded that the resulting circumstances—namely, the survival of some claims that the Board initially deemed to be likely unpatentable—did not play a role in the jurisdiction question. *Id*. (addressing the "two distinct phases" of IPR proceedings, and noting that the IPR proceeding "did not include the non-instituted grounds")

Harmonic further argued that the decision to institute on some grounds, but not others, "takes it out of the realm of an institution decision and into that of a case management decision, which Harmonic asserts we have jurisdiction to review for abuse of discretion." *Id.* at 1366. The Court also rejected this argument:

> Our prior decisions hold that § 314(d) prohibits review of the decision to institute an IPR, *Cuozzo*, 793 F.3d at 1276, as well as the decision to deny institution of an IPR, *St. Jude*, 749 F.3d at 1375–76. A decision to institute on only a subset of the grounds identified in the petition is simply a combination of the two. Although Harmonic labors to categorize the Board's institution decision in this case as a different type of "case management decision," it is no different than the circumstances squarely addressed in our prior decisions. The Board's decision to institute on one prior art ground or another does not raise fundamental questions about the scope of its statutory authority to deem patents unpatentable; it is simply the Board's exercise of its institution authority in a given case. Section 314(d) prohibits our review of such a decision.

Id.

Applying those principles here, appellate review of the Board's decision not to institute on (or later consider) Maruyama and Fujita is not triggered just because the Board provided a rationale with which Appellants disagree. The Board could have remained silent, although, as explained below, the rationale it did provide was sound. Nor is appellate review triggered by any alleged "changed circumstances." As explained below, the materiality of anticipation arguments under Maruyama and Fujita is, at best, doubtful under any construction of "about 5%," and any purportedly changed circumstances are the result of Appellants' legal strategy rather than "shenanigans" by the Board.

Because the Maruyama and Fujita grounds did not survive the institution phase, they were "not part of the review." *Id*. at 1367. Furthermore, the Board's decision not to reconsider (and, therefore, not to later institute IPR on) previously rejected grounds is "simply the Board's exercise of its institution authority." *Id*. at 1366. Appellants cannot convert the Board's unreviewable discretionary decision into an appealable one simply by framing it as a denial of a request for rehearing.

Appellants' alternative request for mandamus relief also should be denied. "A writ of mandamus is a drastic and extraordinary remedy that can only be used in exceptional circumstances amounting to a judicial usurpation of power or a clear abuse of discretion." *Shaw Indus. Gp. v. Automated Creel Sys., Inc.*, 817 F.3d

1293, 1299 (Fed. Cir. 2016) (quoting *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380 (2004) (internal quotations omitted)).

> A writ requires (1) that the petitioner have no other adequate means to attain the desired relief, (2) that the petitioner have a "clear and indisputable" right to the writ, and (3) that the issuing court, in the exercise of its discretion, be satisfied that the writ is appropriate under the circumstances.

Id.

None of the requirements are met here. As articulated in *Shaw*, non-instituted grounds "never become part of the IPR." *Id*. at 300. As a result, the first requirement is not met, since Appellants are not statutorily estopped from raising their arguments in the district courts. More fundamentally, however, as in *Shaw*, Appellants have no "clear and indisputable right to the writ." *Id*. at 1299. As discussed above and in several recent controlling cases, there is no question that the Board had the authority to consider only some of Appellants' arguments in the IPR proceedings, which the Board conducted within its sound discretion.

B. The Board's Decision was not Arbitrary and Capricious

The Board's rehearing denial only can be appealed if, as *Cuozzo* put it, "shenanigans" resulted in an arbitrary and capricious decision. Appellants' request (and appeal of its denial) rest on assumptions that there was a change in circumstances beyond Appellants' control and that the Board somehow abused its discretion. This is not the case. To the contrary, in an effort to sweep in prior art,

Appellants each made the decision to present in their petitions a single, unreasonably broad construction for the term "about 5%." As shown in Section IV.A., this construction runs contrary to the teachings of the '351 patent, Appellants' own prior construction of claim terms involving ranges of concentrations, and basic logic.

Appellants' gambit was successful at first, as the Board initially adopted Appellants' flawed claim construction in its institution decision. But because Appellants elected to ignore the obvious alternative claim construction in their petitions, their arguments for anticipation of Claims 5 and 28 based on Maruyama and Fujita appeared to the Board to be indistinguishable from their other anticipation arguments.[10] Notably, at no point before Appellants' post-Final Written Decision request for rehearing did Appellants challenge the Board's denial of the Maruyama or Fujita grounds as redundant.[11]

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[10] Neptune's preliminary patent owner statements did not address Appellants' unreasonable claim construction of "about 5%." Appellants imply that this suggests acquiescence by Neptune. Appellants' Br., 51. To the contrary, Appellants' proposed construction of that term was simply one of many flaws in their petitions to which space limitations did not permit a preliminary response. A preliminary patent owner response need not take issue with every misstatement or misguided argument; in fact, the patent owner need not file a preliminary response at all. Furthermore, as addressed below, well before Neptune even filed its preliminary responses, Neptune had already proffered the appropriate 2.5%-7.5% construction in the ITC Action.

[11] Aker ***did*** challenge the Board's institution decision, but for reasons unrelated to redundancy. (Aker sought rehearing of the Board's decision not to institute review

The Board properly denied Appellants' belated attempt to inject their Maruyama and Fujita anticipation grounds into the IPR. The Board's decision, far from being arbitrary and capricious, provided sound reasons for denying rehearing:

> Petitioner, in its Petition, did not explain adequately the relative strengths or weaknesses between the applied prior art references. If Petitioner believed that any other grounds set forth in the Petition had certain weaknesses or strengths, as compared to grounds of unpatentability based on Maruyama or Fujita, for example based on alternative claim constructions that Patent Owner might have raised, it was incumbent upon Petitioner to identify those strengths or weaknesses in its Petition. Doing so would have allowed us to recognize and weigh such factors in rendering a decision as to whether to institute review based on the different asserted grounds. Simply proposing different grounds of unpatentability directed to the same subset of claims does not distinguish meaningfully the applied prior art references.

Appx0043-44.

Contrary to Appellants' claim that this would require them to "play whack-a-mole blindfolded" (Appellants' Br., 50), it is entirely reasonable to expect Appellants to address the possibility that the claim term might be construed in a

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of all claims under Ground 1 (anticipation by Beaudoin I)). This request for rehearing did not even mention Maruyama or Fujita, despite the fact it was made in April 2014, several months after Neptune proposed, and the parties fully explored, the 2.5%-7.5% construction of "about 5%" in the parallel ITC Action. This was also several months after the third-party government representative in the ITC Action adopted the same 2.5%-7.5% construction.

way consistent with the specification, Appellants' own prior constructions of other claim terms involving ranges of values, and basic logic.[12]

The Board's denial and its stated reasoning were perfectly sound. In contrast to Appellants' cited cases,[13] even if reasonable minds could disagree as to

[12] Appellants refer to the Board's adoption of the proper construction of "about 5% free fatty acids" as "outcome-determinative" in light of Maruyama and Fujita, contending that anticipation by Maruyama and Fujita is clear under the proper construction. Appellants' Br., 61. To the contrary, neither Maruyama nor Fujita anticipates Claims 5 and 28 under ***any*** construction, and it is far from clear that the Board would have instituted IPR on these grounds even if Appellants had set forth the proper construction as a reasonable alternative. With regard to Maruyama, Appellants relied exclusively on Table 1 for their asserted free fatty acid concentration. Appx0123; Appellants' Br., 51. But the Board correctly noted in its Institution Decision that "Table 1 of Maruyama, however, discloses the lipid composition of ***dried krill***, not the lipid composition of a ***krill extract or solution***." Appx0254 (emphasis added). The Board further dismissed as conclusory the declaration testimony of Appellants' expert that attempted to tie the values in Table 1 to a krill extract. Appx0254-255. With regard to Fujita, the reference does not contain ***any*** measurements of free fatty acids, and Appellants' anticipation argument for Claims 5 and 28 relied exclusively on purported recreations of the Fujita extracts and conclusory declaration testimony regarding the same. Appx0129; Appellants' Br., 51-52. The Board dismissed similar conclusory declaration testimony regarding other lipid concentrations not actually stated in Fujita. Appx0255.

[13] *See* Appellants' Br., 49. *Columbia Falls Aluminum Co. v. EPA* concerned the plainly arbitrary use of a model that "bears no rational relationship to the reality it purports to represent." 139 F.3d 914, 922-23 (D.C. Cir. 1998). *Town of Norwood v. FERC* concerned a commission's arbitrary refusal to establish a new reasonable rate of return to account for the fact that a company was "no longer operating," when the original rate was based on the very risks associated with continued operation. 80 F.3d 526, 535 (D.C. Cir. 1996). These cases stand for the simple proposition that there is no basis for an agency to continue with an outcome-determinative course of action that is "no longer viable," *Id.*, or "bears no rational relationship to [] reality. *Columbia*, 139 F.3d at 923. They are not comparable to

the correctness of its decision, the Board's decision was not the result of any "shenanigans," and it falls far short of being arbitrary and capricious.

CONCLUSION

For the reasons stated above, the Court should reverse the Board's anticipation and obviousness rulings for 26 of the claims at issue and affirm the Board's ruling that Appellants failed to prove invalidity of Claims 5 and 28.

Dated: July 1, 2016

Respectfully submitted,

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the allegedly "changed" circumstances here, which did not likely affect the outcome and which resulted from Appellants' own legal strategy.

United States Court of Appeals for the Federal Circuit

Aker BioMarine AS v. Neptune Technologies and Biore, 2016-1067, -1108, -1111

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I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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